

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of)
)
Diana J. Parsons)
) Examiner:
Continuation-in Part of)
Serial No. 10/047,335)
)
) Group Art Unit:
)
For: METHOD AND PROCESS)
FOR PRODUCING YOUTHFUL-)
APPEARING, SMALL-PORED)
AND SMOOTH SKIN)

Bush Intellectual Property Law Group
300 Corporate Parkway, Suite 2
Birmingham, AL 35242

Honorable Commissioner of Patents
Washington, DC 20231

Dear Sir or Madam:

REMARKS

Applicant has filed a Continuation-In-Part Application simultaneously with the filing of this response to the office action dated September 17, 2003 for application number 10/047,335.

35 U.S.C. § 132 Objection

The Examiner has objected to the April 4, 2002 Preliminary Amendment. The Objection asserts that the change from microseconds to seconds is not supported by the original disclosure.

The Application as originally filed on January 14, 2002 incorporates by reference U.S. Patent No. 6,036,684 issued to Tankovich. (See page 6, lines 20-22). Tankovich teaches that while other embodiments of his invention could be utilized, that an important attribute of the invention is a pulse duration of less than one microsecond (see column 8, lines 7-10 and 15-17 of Tankovich). Since Tankovich explicitly requires a pulse duration of less than one microsecond, by incorporating the Tankovich patent by reference into the disclosure of the original application, the Applicant provided sufficient support for the use of microseconds as the appropriate time unit by which laser pulse durations should be measured.

Simultaneously with the submission of these remarks, Applicant has submitted a Continuation-In-Part Application, including the matter from the April 4, 2002 Preliminary Amendment. Despite this submission, however, Applicant respectfully maintains the position that Examiner's objection to the Preliminary Amendment is erroneous and requests that her objection be withdrawn.

35 U.S.C. § 112 Rejection (New Matter)

The Examiner has rejected claims 9-10 and 27-28 under 35 U.S.C. § 112 as failing to comply with the written description requirement.

Applicant respectfully renews her traversal to the Examiner's objection to the Preliminary Amendment as noted above. If such objection is withdrawn, this rejection will no longer be valid, since the unit of microseconds in the rejected claims will match the unit of microseconds taught in the specification. Furthermore, simultaneously with the submission of these remarks, Applicant has submitted a Continuation-In-Part Application, including the matter from the April 4, 2002 Preliminary Amendment. If the Examiner does not withdraw her objection to the Preliminary Amendment, then the Continuation-In-Part Application provides sufficient support for the use of the unit of microseconds in the rejected claims. Applicant respectfully requests that the Examiner withdraw this objection.

35 U.S.C. § 112 Rejection (Indefiniteness)

The Examiner has rejected claims 1-36 under 35 U.S.C. § 112 as indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. The Examiner's rejection is based upon her position that language from independent claims 1 and 21, "maintaining the dermis in a chronically wounded condition" is vague and indefinite, since it is not clear whether the wound has been prevented from healing. The Examiner also rejects the language from claims 6 and 21, which recite "wherein said production of a chronic wound in the high dermis leaves the epidermis intact." The Examiner's rejection of these claims is based on her position that since the epidermis is the outermost layer and the dermis supports and strengthens the epidermis, that Applicant has not made clear how the dermis could be wounded while leaving the epidermis intact.

Regarding claims 1 and 21, Applicant has modified the language in both claims in the Continuation-In-Part Application filed with these remarks (see claims 1 and 21 of the Continuation-In-Part Application). This change in claim language is supported by the specifications from both the original application and the Continuation-In-Part Application, as both applications explain that the laser process is repeated several times to create a chronic wound in the high dermis (see page 9, lines 28-29 of original application and page 9, lines 4-5 of the Continuation-In-Part Application). The Applicant explains in the Continuation-In-Part Application that the skin biopsy studies performed by Tankovich et al. resulted in no significant injury to the skin but the formation of new collagen fiber in the upper part of the dermis immediately below the epidermal basal membrane. The Applicant notes that while Tankovich et al. had no explanation for the effect described above, that the Applicant's independent studying of the effect has revealed that the selective wounding of the high dermis is responsible for the formation of new collagen fiber. Furthermore, the Applicant discovered that the shorter the laser's wavelength, the deeper the injury in the epidermis. The Applicant further explains that in the Tankovich patent, the extent of the injury in the high dermis resulting from the exploding carbon particles in the epidermis is insufficient to induce adequate collagen deposition during wound healing. See page 4, line 17 through page 5, line 3 of the Continuation-In-Part Application. Both claims now definitely and distinctly claim the method by which the high dermis is maintained in a chronically wounded condition. In both claims 1 and 21, the method requires that a plurality of wounding events prevents the wound from healing. It is this continued process of wounding that prevents the wound from healing and maintains the high dermis selectively in a chronically wounded

condition, leaving the epidermis intact. The chronic wounding produces sufficient new collagen in the high dermis to produce a beneficial effect.

Regarding claims 6 and 21, Applicant has added language to the Continuation-In-Part Application. Applicant explains that because of the wavelength of the laser used in the invention, the emitted pulses of heat are deposited in the high dermis while the low energy of the laser causes those pulses not to burn the epidermis (see page 9 line 22 through page 10 line 1 of the Continuation-In-Part Application). This failure to wound the epidermis is established in the Tankovich patent, incorporated by reference into both the original application and the Continuation-In-Part Application.

Regarding claim 10, Applicant has amended claim 9 in the Continuation-In-Part Application to shift the upper boundary from 1000 nM to 1200 nM (see claim 9 of Continuation-In-Part Application). Applicant has also modified the specification to reflect this change (see page 8, lines 23-24 of Continuation-In-Part Application). The broadening of claim 9 now causes dependent claim 10 to fall within the scope of claim 9 and thus corrects the indefiniteness rejected by the Examiner.

35 U.S.C. § 102 Rejections

The Examiner has rejected claims 1-7, 11-12, 14, 16, 19-22, 29-30, 32, 34, and 35 under 35 U.S.C. § 102(b) as anticipated by the Kye reference; claims 1, 5-8, and 17-20 under 35 U.S.C. § 102(b) as anticipated by the Obagi reference; and claims 1-7, 11-12, 14, 16, 19-22, 29-30, 32, and 33-35 under 35 U.S.C. § 102(b) as anticipated by the Ho reference.

According to patent law, anticipation under § 102 “requires the presence in a single prior art disclosure of each and every element of a claimed invention.” Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747, 3 U.S.P.Q.2d 1766, (Fed. Cir. 1987). Further, “every element of the claimed invention must be identically shown in a single reference.” Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 677, 7 U.S.P.Q.2d 1315, (Fed. Cir. 1988).

Regarding the Kye reference, every claim of the present invention requires a chronically wounded condition caused by a plurality of wounding events, since both independent claims state such a requirement. Kye does not teach multiple laser treatments, but only teaches one laser treatment. Since Kye does not teach or suggest the limitation of multiple treatments, the § 102 rejection must be withdrawn. Secondly, claim 6 and claim 22 both require that the treatments leave the epidermis intact. Kye does not teach the leaving of the epidermis intact. Since Kye does not teach or suggest the limitation of leaving the epidermis intact, the § 102 rejection as it is applied to claim 6 and claim 22 must be withdrawn.

Regarding the Obagi reference, every claim of the present invention requires a wounding of the high dermis, since both independent claims state such a requirement. The present invention achieves such wounding through the use of a laser. Obagi teaches treatment of the skin with the use of a lamp. Obagi does not teach the wounding of the patient’s skin with a laser, but merely the exposure of the patient’s skin to light, explaining that “[e]xposure to light acts to stimulate a total regeneration of the treated area and aids in correcting the damage (see column 2, lines 60-62 of Obagi). While the present invention requires the use of a laser to effect wounding events, Obagi teaches the

use of nothing more than a lamp (see column 5, lines 45-58). Since Obagi does not teach wounding of the high dermis, and Obagi's lamp could not satisfy wounding of the high dermis, Obagi does not teach or suggest this limitation and thus the § 102 rejection must be withdrawn. Secondly, every claim of the present invention requires the treatment of the patient's skin with a topical cream before and after wounding, since both independent claims state such a requirement. Obagi only teaches pre-treating the skin, but does not teach the treatment of the skin after wounding. Since Obagi does not teach or suggest post-wounding treatment of the skin with a topical cream, the § 102 rejection must be withdrawn. Thirdly, claim 6 requires that the treatments leave the epidermis intact. The procedure taught in Obagi's patent requires that after the area has been irradiated by the lamp, that the exposed skin is peeled and removed. See column 2, lines 57-62 of Obagi. Since Obagi does not teach or suggest the limitation of leaving the epidermis intact, the § 102 rejection as it is applied to claim 6 must be withdrawn.

Regarding the Ho reference, every claim of the present invention requires a chronically wounded condition caused by a plurality of wounding events, since both independent claims state such a requirement. Ho does not teach multiple laser treatments, but only teaches one laser treatment. Since Ho does not teach or suggest the limitation of multiple treatments, the § 102 rejection must be withdrawn. Secondly, claim 6 and claim 22 require that the treatments leave the epidermis intact. Ho does not teach the leaving of the epidermis intact. Since Ho does not teach or suggest the limitation of leaving the epidermis intact, the § 102 rejection as it is applied to claim 6 and claim 22 must be withdrawn.

35 U.S.C. § 103 Rejections

The Examiner has rejected claims 8, 13, 15, 23-26, and 31 under 35 U.S.C. § 103(a) as obvious over the Ho reference in view of the Obagi reference; claims 9-10, 27-28, 29, and 36 under 35 U.S.C. § 103(a) as obvious over the Ho reference in view of the Tanovich reference; and claims 1-7, 9-10, 19-21, 27-28, 34-35, and 36 under 35 U.S.C. § 103(a) as obvious in view of the Tanovich reference in view of the Grevelink reference.

Obviousness according to § 103 can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). Additionally, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references. Ex parte Clapp, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985).

Regarding the first obviousness rejection, the Examiner takes the position that since Ho teaches the use of a laser and Obagi teaches multiple lamp treatments, that it would have been obvious to one of ordinary skill in the art to have combined the two references and invent multiple laser treatments. However, a principal requirement of the present invention is that the dermis is chronically wounded through multiple laser treatments. This chronic wounding is a requirement of every claim of the present invention, since both independent claims state such a limitation. The benefits of this

requirement are explained in the specification of the original application to sustain rejuvenation of the skin and treatment of skin conditions (see page 9, lines 1-3 of the original application). While the original application provides sufficient support to explain the benefit of chronically wounding the skin, the Continuation-In-Part application is more specific in this explanation, as it adds that this state of sustained rejuvenation is achieved by the production of new collagen in the skin above the level of the inherent collagen, a result that is obtained due to the chronic wounding (see page 8, lines 8-11 of Continuation-In-Part Application). Neither a single laser treatment nor multiple exposures to a lamp result in the chronic wounding of the skin, and thus neither Ho nor Obagi teach the beneficial effects taught by the Applicant. Since neither Ho nor Obagi teach or suggest chronic wounding of the dermis, the § 103 rejection must be withdrawn.

Regarding the second obviousness rejection, the Examiner takes the position that since Ho teaches the use of tretinoin cream and Tanovich teaches the use of specific laser parameters, that it would have been obvious for one of ordinary skill in the art to have combined the two references and invent a process that used specific laser parameters along with tretinoin cream. As noted above, a principal requirement of the present invention is that the skin is chronically wounded through multiple laser treatments. Neither Ho nor Tanovich teaches chronic wounding of the patient's skin and thus, as with the previous rejection, neither reference teaches the beneficial effects taught by the Applicant. Since neither Ho nor Tanovich teach or suggest chronic wounding of the dermis, the § 103 rejection must be withdrawn.

Regarding the third obviousness rejection, the Examiner takes the position that since Tanovich teaches the use of a laser and Grevelink teaches the pretreatment of the patient's skin, that it would have been obvious for one of ordinary skill in the art to have combined the two references and invent a process that used a laser along with pretreatment of the patient's skin. As noted in the two above paragraphs, a principal requirement of the present invention is that the skin is chronically wounded through

multiple laser treatments. Neither Tanovich nor Grevelink teaches chronic wounding of the patient's skin and thus, as with the previous two rejections, neither reference teaches the beneficial effects taught by the Applicant. Since neither Tanovich nor Grevelink teach or suggest chronic wounding of the dermis, the § 103 rejection must be withdrawn.

CONCLUSION

Applicant respectfully submits that the alterations made in the Continuation-In-Part Application and remarks place the case in condition for allowance and, therefore, Applicant requests such allowance.

Respectfully submitted,

Bush Intellectual Property Law Group

by:



Gerald M. Walsh

Reg. No. 34,946

Attorney for Applicant

Phone: (205) 972-1045

Fax: (205) 972-0163